

AMENDMENTS TO THE CLAIMS

This listing of the claims will replace all prior listings and versions of the claims.

1. (Currently amended) A method of qualifying breast cancer status in a human subject comprising:

(a) measuring the amount of at least one biomarker in a sample from a subject, wherein the biomarker is measured by surface enhanced laser desorption/ionization (SELDI), and wherein the biomarker is selected from the group consisting of:

Marker I (BC1) having a molecular weight of about 4283 daltons,

Marker II (BC2) having a molecular weight of about 8126 daltons,

Marker III (BC3) having a molecular weight of about 8932 daltons,

Marker IV having a molecular weight of about 4465 daltons,

Marker V having a molecular weight of about 4060 daltons,

Marker VI having a molecular weight of about 8322 daltons,

Marker VII having a molecular weight of about 17046 daltons,

Marker VIII having a molecular weight of about 17696 daltons,

Marker IX having a molecular weight of about 10240 daltons,

Marker X having a molecular weight of about 5891 daltons,

Marker XI having a molecular weight of about 8426 daltons,

Marker XII having a molecular weight of about 7541 daltons,

Marker XIII having a molecular weight of about 9413 daltons, and

Marker XIV having a molecular weight of about 16244 daltons,

and combinations thereof,

(b) wherein an increase or decrease in the amount of the marker as compared to a control is indicative of a change in the breast cancer status, and wherein mass accuracy of SELDI is within +/-0.15 percent of the disclosed molecular weight value.

2. (Previously Presented) The method of claim 1 further comprising:

(c) managing subject treatment based on the breast cancer status.

3. (Previously Presented) The method of claim 2 wherein managing subject treatment is selected from ordering more tests, performing surgery, and taking no further action.

4. (Previously Presented) The method of claim 2 further comprising:
 - (d) measuring at least one biomarker after subject management.
5. (Previously Presented) The method of claim 1 wherein the breast cancer status is selected from the group consisting of the subject's risk of cancer, the presence or absence of disease, the stage of disease, and the effectiveness of treatment.
6. (Cancelled)
7. (Currently amended) The method of claim 1 wherein at least one biomarker is selected from Marker I (BC1), Marker II (BC2), and Marker III (BC3).
8. (Previously Presented) The method of claim 1 further comprising measuring a known breast cancer biomarker in a sample from the subject and correlating measurement of the known biomarker and the measurement of any one or more of Markers I through XIV with breast cancer status.
9. (Previously Presented) The method of claim 8 wherein the known biomarker is selected from CA 15.3 or CA 27.29.
10. (Currently amended) The method of claim 1 comprising measuring Marker I (BC1), Marker II (BC2), and Marker III (BC3).
11. (Previously Presented) The method of claim 10 further comprising measuring a known breast cancer biomarker in a sample from the subject and correlating measurement of the known biomarker and the measurement of any one or more of Markers I through XIV with breast cancer status.
12. (Previously Presented) The method of claim 11 wherein the known biomarker is selected from CA 15.3 or CA 27.29.

13. (Previously Presented) The method of claim 1 wherein measuring comprises:

- (a) providing a subject sample of blood or a blood derivative;
- (b) capturing one or more of Markers I through XIV from the sample on a surface of a substrate comprising capture reagents that bind the protein biomarkers.

14.-15. (Cancelled)

16. (Previously Presented) The method of claim 13 wherein the substrate is a microtiter plate comprising biospecific affinity reagents that bind one or more of Markers I through XV and the protein biomarkers are detected by immunoassay.

17. (Previously Presented) The method of claim 1 wherein measuring is selected from detecting the presence or absence of the biomarkers(s), quantifying the amount of marker(s), and qualifying the type of biomarker.

18. (Previously Presented) The method of claim 1 wherein at least one biomarker is measured using a biochip array.

19. (Previously Presented) The method of claim 18 wherein the biochip array is a protein chip array.

20. (Cancelled)

21. (Previously Presented) The method of claim 18 wherein at least one biomarker is immobilized on the biochip array.

22-23. (Cancelled)

24. (Previously Presented) The method of claim 1 wherein the correlating is performed by a software classification algorithm.

25. (Previously Presented) The method of claim 1 wherein the sample is selected from blood, serum and plasma.

26. (Currently amended) A method comprising:

(a) measuring a plurality of biomarkers in a sample from the a human subject, wherein each biomarker is measured by surface enhanced laser desorption/ionization (SELDI), and wherein the plurality of biomarkers is selected from the group consisting of:

Marker I (BC1) having a molecular weight of about 4283 daltons,

Marker II (BC2) having a molecular weight of about 8126 daltons,

Marker III (BC3) having a molecular weight of about 8932 daltons,

Marker IV having a molecular weight of about 4465 daltons,

Marker V having a molecular weight of about 4060 daltons,

Marker VI having a molecular weight of about 8322 daltons,

Marker VII having a molecular weight of about 17046 daltons,

Marker VIII having a molecular weight of about 17696 daltons,

Marker IX having a molecular weight of about 10240 daltons,

Marker X having a molecular weight of about 5891 daltons,

Marker XI having a molecular weight of about 8426 daltons,

Marker XII having a molecular weight of about 7541 daltons,

Marker XIII having a molecular weight of about 9413 daltons, and

Marker XIV having a molecular weight of about 16244 daltons,

wherein mass accuracy of SELDI is within +/-0.15 percent of the disclosed molecular weight value.

27. (Currently amended) The method of claim 26 wherein the plurality includes Marker I (BC1), Marker II (BC2), and Marker III (BC3).

28. (Previously Presented) The method of claim 26 further comprising measuring a known biomarker.

29. (Previously Presented) The method of claim 26 wherein the known biomarker is selected from CA 15.3 or CA 27.29.

30. (Cancelled)

31. (Previously Presented) The method of claim 26 wherein the sample is selected from blood, serum and plasma.

32.-57. (Cancelled)

58. (Currently amended) A method of determining if a human subject has breast cancer comprising:

(a) measuring at least one biomarker in a sample from the subject, wherein the biomarker is measured by surface enhanced laser desorption/ionization (SELDI); wherein the biomarker is selected from the group consisting of:

Marker I (BC1) having a molecular weight of about 4283 daltons,
Marker II (BC2) having a molecular weight of about 8126 daltons,
Marker III (BC3) having a molecular weight of about 8932 daltons,
Marker IV having a molecular weight of about 4465 daltons,
Marker V having a molecular weight of about 4060 daltons,
Marker VI having a molecular weight of about 8322 daltons,
Marker VII having a molecular weight of about 17046 daltons,
Marker VIII having a molecular weight of about 17696 daltons,
Marker IX having a molecular weight of about 10240 daltons,
Marker X having a molecular weight of about 5891 daltons,
Marker XI having a molecular weight of about 8426 daltons,
Marker XII having a molecular weight of about 7541 daltons,
Marker XIII having a molecular weight of about 9413 daltons, and
Marker XIV having a molecular weight of about 16244 daltons,
and combinations thereof

(b) wherein an increase or decrease in the amount of the marker as compared to a control is indicative of breast cancer, and wherein mass accuracy of SELDI is within +/-0.15 percent of the disclosed molecular weight value.

59. (Previously Presented) The method of claim 58 further comprising:
(c) managing subject treatment based on the presence or absence of breast cancer.